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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/757,680	Applicant(s) MORRIS ET AL.	
	Examiner Kathleen Sonnett	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☒ Claim(s) 7 17, and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7/24/2006 have been fully considered but they are not persuasive.
2. In response to applicant's arguments, the recitation "for a medical device" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).
3. Applicant also argues that the clamp system of Forrer permits only gross adjustment and is not appropriate for actuation of a guidewire or actuator sleeve. However, the examiner respectfully disagrees. The term "gross" is a relative term and machining tools used in industry are often employed with as strict of tolerances as those used in the medical field.
4. In response to applicant's argument that the structure given to the actuation sleeve and medical device in the preamble is part of the patentability analysis for the claims, the examiner agrees. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. This structure recited in the preamble has been considered in so far as how it limits the structure of the proximal actuator. That is, the proximal actuator must be capable of being removably attachable to such a device in a way that

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allows longitudinal movement of the actuator sleeve relative to the wire in order to actuate a medical device attached to the sleeve.

5. In response to applicant's mention of priority predating Grover (U.S. 6,193,125 issued 2/21/2001), applicant only claims priority to provisional application (60/440,932). Additionally, a proximal actuator with retaining devices that support the lateral attachment of a medical device in the proximal actuator, or the use of spring clips in such a device, are not disclosed in any of the commonly assigned patent applications (10/346729, 09/875342, 09/660380, 09/376120, 09/540959, 09/376120) and therefore, the earliest priority date of all of the claims is that of the provisional application (60/440,932) which is 1/17/2003.

6. The amendment to the specification has overcome the previous objection for minor informalities (numbering of elements in [00142]).

Specification

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the proximal actuator does not include structure that would render it impossible to longitudinally insert a sleeve into the retaining device if it is open. Claims 10, 17, and 18 include the limitation "transversely attachable and not longitudinally attachable" or "laterally attachable and detachable and not longitudinally attachable".

Claim Objections

8. **Claims 7 and 45** are objected to because of the following informalities: the first retaining device is movably mounted the body according to claims 1 and 39. Claims 7 and 45 seem to contradict this as the first retaining device is in a fixed position. Appropriate clarification or correction is required.

9. **Claim 17** is objected to because of minor informalities. The words "to and detachable" should be inserted between "attachable" and "from" in line 4 of claim 17.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **Claims 1-16, 17, 18-31, 39-52** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

12. Regarding independent claims 1, 16, 18, 39 and therefore the claims that depend from these independent claims (1-15, 17, 19-31, 40-52), claims 1 and 16 include the limitation "an actuator body having, movably mounted thereon, a first and a second retaining device. Claims 18 and 39 include the limitation "a body with a handle, said body having, movably mounted thereon, a first and second retaining device". The invention as described in the specification does not disclose that both the first and second retaining devices are movably mounted on the actuator body. From the description in the specification, the body is being considered some portion of element (314), either the handle or the upper portion that houses the sleeve (16). However, only the distal retaining device is movably mounted to the body while the proximal retaining member is fixedly mounted to the body in both the embodiments shown in figs. 36 and 37 (see also par. [00140-00143] of instant specification).

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13. Claims 10, 17, and 18 contain further subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 10, the limitation "transversely attachable and not longitudinally attachable" contains new matter. In claims 17 and 28, the limitation "laterally attachable and detachable and *not longitudinally attachable*", contains new matter (emphasis added). It appears that this is meant to be a negative limitation. However, the specification does not disclose any structure on the proximal actuator that would prohibit longitudinal attachment of the elongated actuation sleeve and wire. That is, the retaining devices can be opened and a user could either attach the actuation sleeve laterally to the retaining devices or longitudinally. Once the actuation sleeve is positioned, the user could then release the retaining devices so that they close down on the actuation sleeve. For example, imagine a round clamp with a circular aperture, the clamp opening into a C-shape. A tube can be placed into that open C-shaped clamp laterally through the opening of the C (the now open portion of the previously circular O-shape). The tube can also be placed into that open C-shaped clamp by sliding the tube longitudinally through the central aperture of the clamp while the clamp is still opened. No embodiment is presented wherein an actuation sleeve could not be longitudinally attachable to the retaining devices.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. **Claims 1, 7-9, 15-16, 32-34, 39, and 45-48** are rejected under 35 U.S.C. 102(b) as anticipated by Forrer (U.S. 4,576,529) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Forrer in view of Grover (U.S. 6,193,125).

16. Regarding claims 1 and 16, Forrer discloses an actuator body (9) having, movably mounted thereon, a first and second retaining device such that, if an actuation sleeve with wire are attached, longitudinal movement of an actuator sleeve relative to a wire is caused by special movement between the first and second retaining devices. The first and second retaining devices are removably attachable to the actuation sleeve and the second retaining device is moveable relative to the first retaining device (col. 1 ll. 34-41).

17. Regarding claim 39, Forrer discloses a body with a handle grip portion (9) (left most portions of 9 in fig. 2 or 3 considered the grip portion), the body having, movably mounted thereon first and second retaining devices that are attachable to an actuation sleeve. The second retaining device is moveable relative to the first retaining device.

18. Regarding claim 32, Forrer discloses a deployment handle removably attachable to an expandable device, the deployment handle comprising, a body with a handle grip portion (20) including a sleeve (6), a first retaining device (1) affixed to the sleeve and removably attachable to an actuation sleeve, a sliding member (14) with a first end positionable through the aperture of the sleeve, a second retaining device (1') affixed to the second end of the sliding member and removably laterally attachable to an actuation sleeve, and a control actuator (col. 2 lines 57-60) movably engaging the first end of the sliding member within the aperture such that the control actuator moves the second retaining member from a first position to a second position relative to the first retaining device (col. 1 lines 34-41). Note that the body is now being considered element (20).

19. Regarding the lateral attachment of an actuation sleeve to the retaining devices as claimed in claims 1, 16, 32, and 38, depending on the size of the actuation sleeve, lateral attachment is possible since the device, if small enough, can be placed in aperture (2) by sliding the sleeve through the channel (3) and then the aperture is reduced in size by clamping screw (4) biases the channel closed. Forrer discloses that the two legs of each retaining device are clamped together by clamping screw (4) (col. 2 ll. 45-49). It is reasonable to assume that channel (3) can be opened slightly since a clamping screw can bias the legs together. That is, the legs are flexible enough that a screw can move them towards each other (col. 1 ll. 44-49).

20. Alternatively, if the actuation sleeve is too large to fit channel (3), Grover discloses a retaining device that uses a spring clip so that a tool can be laterally placed and locked into the retaining device. Grover discloses that this configuration is advantageous because the tool can be inserted easily into the retaining device and automatically locked in place with one motion and then unlocked and removed with another single motion (col. 4 ll. 30-45). This can be achieved by a vertical motion (lateral) as opposed to a longitudinal motion. Using this kind of operation for the retaining device of Forrer would simplify the operation of the device in that it would allow a device to be laterally attached to the jaws without having to tighten a clamping screw. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Forrer to include retaining clips that allow lateral attachment of a sleeve that would not fit through channel (3) as made obvious by Grover in order to gain the advantage of being able to place and lock a tool in the retaining devices in one motion without having to employ a clamping screw.

21. Regarding claims 15, 33, and 34, the device disclosed by Forrer, or alternatively, the modified device of Forrer in view of Grover, meets all of the structural limitations positively recited in claims from which claims 15, 33, and 34 depend. Furthermore, Forrer is capable of

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opening and closing an expandable frame by virtue of the relative lateral movement of the first and second retaining devices. A medical device used to control an expandable frame wherein relative lateral movement of two members causes the configuration of the frame to change can be positioned in the retaining members of the Forrer device and actuated.

22. Regarding claims 7-9, the device disclosed by Forrer, or alternatively, the modified device of Forrer in view of Grover includes a first retaining device that can be in a fixed position and a second retaining device that is longitudinally movable from a first position to a second position relative to the first retaining member (col. 1 ll. 34-41).

23. Regarding claim 45, the first retaining device is in a fixed position (col. 1 lines 37-41). Forrer discloses that one or both of the jaw members are movable backward and forward as either one or both of the jaw members are threaded to engage with the rotatable spindle.

24. Regarding claim 46, the second retaining device is longitudinally movable from a first position to a second position relative to the first retaining member.

25. Regarding claims 47 and 48, Forrer is capable of opening and closing an expandable frame by virtue of the relative lateral movement of the first and second retaining devices. A medical device used to control an expandable frame wherein relative lateral movement of two members causes the configuration of the frame to change can be positioned in the retaining members of the Forrer device and actuated.

26. Claims **11-14, 35-38, and 49-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Forrer in view of Grover. Forrer discloses retaining devices comprising two legs formed by slot (3) that are fixed together with a clamping screw (4). The retaining devices each have an alignment indicator comprising the channel defined by aperture (2) (see Fig. 1a). Forrer fails to disclose that the first and second retaining devices are spring loaded clips.

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27. However, Grover et al. discloses that it is old and well known in the art to include spring loaded clips (col. 4 lines 37-44 and col. 1 lines 61-col. 2 line 3) that hold a tool and could hold an actuation sleeve (12) in place after it is connected to a device holder. The spring loaded clips allow for rapid entry of tools into the support and securing of the tool. Grover et al. further discloses that the spring loaded clips provide a means for automatically locking the tool into the holder with the same motion used to insert it and automatically unlocking the tool with the same motion used to remove it (col. 4 lines 36-40). The two legs disclosed by Forrer could be changed to spring loaded clip assemblies so that the clamping screw would not be needed in order to lock the device into the clamp assembly after it has been placed in channel (2). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Forrer to substitute a spring loaded clip, made obvious by Grover et al., for the clamping screw assembly in order to gain the advantage of being able to lock the tool into the holder with the same motion used to insert it.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
9/14/2005


GLENN K. DAWSON
PRIMARY EXAMINER

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